AUG 2 4 2011

Section 5: 510(k) Summary

Submitter:

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Device:

Trade Name:	Cardiac Outpatient Real -time ECG (CORE™)
Common Name:	Arrhythmia Detector and Alarm
Classification:	Detector and Alarm, Arrhythmia
Product Code:	DSI, DSH, DPS
Regulation:	870.1025, 870.2800, 870.2340
Class:	II, Special Controls

Predicate Devices:

The following are the predicate devices chosen to demonstrate substantial equivalence:

1. Card Guard Scientific Survival, Ltd. CG-6108 Continuous ECG Monitor & Arrhythmia Detector, cleared by the FDA under 510(k) number K071995; Product Classification Code DSI, Regulation 870.1025.
2. Card Guard Scientific Survival, Ltd. King Of Hearts Express+AF monitor, cleared by the FDA under 510(k) number K020825 Product Classification Code DSH, Regulation 870.2800.
3. Monebo Technologies, Inc. Monebo Automated ECG Analysis And Interpretation Software Library, Version 3.0, cleared by the FDA under 510(k) number K062282 Product Classification Code DPS, Regulation 870.2340.
4. Applied Cardiac System The Holter Reporter as cleared by the FDA under 510(k) number K860249; Product Classification Code DPS, Regulation 870.2340.

5. Memtec Corp. Model 950-12L as cleared by the FDA under 510(k) number K102723; Product Classification Code MWJ, Regulation 870.2800.
6. Burdick Corp. EK10 Electrocardiograph (non-interpretive), as cleared by the FDA under 510(k) number K870880; Product Classification Code DPS, Regulation 870.2340.

Device Description:

The ACS Cardiac Outpatient Real Time ECG (CORE™) monitor is a multipurpose device designed with the ability to perform: a 2-lead (2 or 3-electrode) Mobile Cardiac Outpatient Telemetry complete with Arrhythmia Detection and Alarm for up to 30 days; a 24-hour or longer 3-lead (5-electrode) or a resting 12-lead (10-electrode) EKG. The ambulatory device may be used on an outpatient basis with remote clinician data analysis as well as use within the physician office setting by a medical professional.

The CORE™ monitor is comprised of 1) a single component ECG monitor with an integrated cellular modem and 2) an interface to four independent cable configurations through a single connector. The CORE™ device automatically changes functionality when a specific cable with the same form factor is inserted with the following configurations:

- 3-wire, ambulatory, snap electrode cable invokes a 1, or 2-lead MCT mode (Lead I, II - no anterior views).
- 5-wire, ambulatory, snap electrode cable invokes the Holter 3-lead mode by default (up to 5-leads are available with anterior views).
- 10-wire, resting (lengthened for full body), alligator clip electrode cable invokes the Resting 12-lead EKG mode (8-channels; derived Leads III, aVF, aVR, aVL).
- A USB cable invokes the PC communication service mode. Cable is interchangeable with ECG lead sets requiring disconnection from the body before connection to an external device can be made.

The built-in cellular modem technology pushes and pulls information to and from the device in a HIPAA compliant fashion using the cryptographic protocol; Transport Layer Security (TLS). Additional data integrity is performed by Error Correction Coding (ECC) and MD5 hash sums.

The CORE™ device houses a microprocessor for running the algorithm and an Application Specific Integrated Circuit (ASIC) for controlling the CORE™ device, a rechargeable battery, real time ECG Arrhythmia Detection using built-in hardware DSP engine in any mode, ECG capture circuitry provided by the ASIC and the multiple components, GSM/GPRS/EGPRS/WCDMA/HSPA network transceivers for cellular communication, Cellular SIM card, high-capacity SD flash card (up to 1024 GB), internal EEPROM, GPS module, a Bluetooth transceiver and a Zigbee (IEEE 802.15.4) transceiver for bi-directional communication with external devices, a full-color LCD touch screen display, 5-button keyboard, Power and Event button, 3-axis accelerometer, RGB

color LED indication module, speaker/microphone, external battery charger, and a USB device port.

The CORE™ device utilizes an embedded algorithm developed by Applied Cardiac Systems, Inc. to analyze ECG signals in real-time. Upon detection of an arrhythmic or patient-activated event, the ECG signal is transmitted wirelessly via the cellular network to a remote Monitoring Center for additional analysis and intervention by a clinician. When cellular service is unavailable, the event will be stored until such time the cellular network becomes available or the patient transmits the data using a land telephone line.

When in the resting 12-lead EKG mode, the device can capture and display 12 channels of ECG. The ECG can be streamed in real-time to a PC wirelessly via the 802.15.4 network transceiver to be displayed, printed, and stored. An embedded SQL database is used in the device for ECG storage and reporting in all modes – MCT, Holter, and resting 12-lead.

Intended Use:

The CORE™ device is intended for outpatient use with remote clinician data analysis (MCT and Holter modes) as well as use within the physician office setting by the medical professional (resting EKG mode). The CORE™ device will provide continuous measurement of heart rate and rhythm over several days, detecting asymptomatic events as well as manual recordings and transmitting them immediately to a remote monitoring center, even when the patient is ambulatory, allowing timely intervention. The CORE™ device can be used for evaluation of recurrent unexplained episodes of presyncope, palpitations, dizziness or when a cardiac arrhythmia is suspected as the cause of the symptoms. The MCT, Holter and Resting 12-lead EKG modes are intended for use on adult patients only.

Indications for Use:

1. MCT Mode: Use on adult patients who experience transient or non-transient symptoms that may suggest cardiac arrhythmias. The arrhythmia detector and alarm device monitors an electrocardiogram and is designed to produce a visible or audible signal or alarm when Ventricular Fibrillation/Flutter, Atrial Fibrillation/Flutter, Pause (Asystole), Bradycardia, or Tachycardia occurs.
2. Holter Mode: Use on adult patients experiencing palpitations, syncope, pre-Syncope, dizziness, arrhythmia, bradycardia, tachycardia, angina, ischemia and paced ECG.
3. Multi-Lead Resting EKG Mode: Use on adult patients for acquiring, storing and viewing/printing of up to twelve (12) leads of patient ECG waveforms through surface electrodes adhered to the patient's body.

Contra-indications for use:

1. Patients with potentially life-threatening arrhythmias who require inpatient monitoring; and patients who the attending physician thinks should be hospitalized.

2.

5-1: CORE™ Device Comparison to Predicate Tables:

5-1-1: CORE™ vs. CG-6108 (K071995)

Table compares the MCT mode device functionality	Applied Cardiac Systems, Inc. The CORE™ (Subject Device)	Card Guard Scientific Survival, Ltd. CG-6108 (Predicate Device)
Manufacturer	Applied Cardiac Systems, Inc.	Card Guard Scientific Survival, Ltd.
510(k) Number	Class II, DSI, 870.1025, DSH, 870.2800, DPS, 870.2340	K071995 Class II, DSI. 870.1025
Intended Use	The MCT mode of the CORE™ device is intended for outpatient use with remote clinician data analysis as well as use within the physician office setting by the medical professional. The CORE™ device will provide continuous measurement of heart rate and rhythm over several days, detecting asymptomatic events as well as manual recordings and transmitting them immediately to a remote monitoring center, even when the patient is ambulatory, allowing timely intervention. The CORE™ device can be used for evaluation of recurrent unexplained episodes of pre-syncope, palpitations, dizziness or when a cardiac arrhythmia is suspected as the cause of the symptoms. The CORE™ device is intended for use on adult patients.	Intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia.
Anatomical Sites	Chest	Chest
Environment of Use	Outpatient (home) or Physician's Office	Home or Physician's Office
Analog/Digital	Digital	Digital
Input Impedance (Ohm)	5 Megohms (min)	20 MΩ
Electrode Configuration	3-lead /3-electrode	3-lead/3-electrode
Frequency Response	0.05 - 40 Hz	0.05 - 40 Hz
CMRR (dB)	100 (min) dB 115 (typical) dB	60
Input Dynamic Range (mVp-p)	1.75 V ± 1 µV	6
DC offset correction (mV)	± 300mV (25µV inherent)	± 150
Band Width (Hz)	0.05 - 100Hz	0.05 - 40Hz
Pacemaker Pulse Marker	Yes	Yes
QRS Detection Sensitivity	Summary Results of AHA and MIT Testing Database | QRS Se | QRS +P	Not available

	<table><tr><td>**AHA**</td><td>97.84</td><td>99.55</td></tr><tr><td>**MIT-BIH**</td><td>98.96</td><td>99.27</td></tr><tr><td>**NST**</td><td>90.84</td><td>86.83</td></tr></table> AHA - The American Heart Association Database for Evaluation of Ventricular Arrhythmia Detectors MIT-BIH - The Massachusetts Institute of Technology-Beth Israel Arrhythmia Database NST - The Noise Stress Database Se - Sensitivity: True Positive/True Positive + False Negative +P - Positive Predictivity: True Positive/True Positive + False Positive	
Power / Noise Ratio	50nV/rt-Hz at 75µA	Not available
System Communication/Monitoring	Continuous	Continuous
Lead Displacement Detection	Yes	Yes
Maximum Storage Memory	64GB (30+ days)	24 hours
Data Transmission	Cellular Transmission	Cellular Transmission
Includes Transtelephonic Capability	Yes	Yes
Heart Rate Indicators	Yes	Yes
Alarm System	Yes	Yes
Retrieval of Digital Holter Data	30 days	48 Hours
Maximum Days for Holter Analysis	30 days	7 Days
Auto Detect/Auto Send	Yes	Yes
Manual Trigger	Yes	Yes
Power Input/Battery Type	3.7V Li-ion	3.6V AA
Battery Life	3 - 7 days	3 - 7 Days
Low Battery Indication	Yes	Yes
Enclosure	Molded Plastic	Molded Plastic
ST Deviation	NEB Configuration	NEB Configuration
Number of Channels	1, 2 or 3	3
Number of Electrodes	3	4
Number of Lead Sets	1	1
Storage Type (Digital or Tape)	Digital	Digital
Operating Temperature Range	0 to +45 °C	+10 to +40°C (50 to 104°F)
Transport & Storage Temperature	0 to 65°C	20 to +65°C (-4 to 149°F)
Relative Humidity	10% - 95% Non-condensing	30% – 85%
Dimensions	5.3 x 2.8 x .8 inches	75 x 58 x 23 mm (max.)
Weight	7 oz	54 gr
ECG Algorithm	Applied Cardiac Systems, Inc. Automated ECG Analysis and Interpretation Software	Proprietary

Real-Time ECG interpretation algorithm	Ventricular Fibrillation/Flutter, Atrial Fibrillation/Flutter, Pause (Asystole), Bradycardia, Tachycardia	Atrial Fibrillation/Flutter, Pause, Pause, Bradycardia, Tachycardia

5-1-2: CORE™ vs. King of Hearts Express+AF (K020825)

Tables compare the Alarms and Triggers functionality for MCT mode	Applied Cardiac Systems, Inc. The CORE™ (Subject Device)	Card Guard Scientific Survival, Ltd. King of Hearts Express+AF (Predicate Device)
Manufacturer	Applied Cardiac Systems, Inc.	Card Guard Scientific Survival, Ltd.
510(k) Number	Class II, DSH, 870.2800, DSI, 870.1025, DPS, 870.2340	K020825 Class II, DSH, 870.2800
Intended Use	The MCT mode of the CORE™ device is intended for outpatient use with remote clinician data analysis as well as use within the physician office setting by the medical professional. The CORE™ device will provide continuous measurement of heart rate and rhythm over several days, detecting asymptomatic events as well as manual recordings and transmitting them immediately to a remote monitoring center, even when the patient is ambulatory, allowing timely intervention. The CORE™ device can be used for evaluation of recurrent unexplained episodes of pre-syncope, palpitations, dizziness or when a cardiac arrhythmia is suspected as the cause of the symptoms. The CORE™ device is intended for use on adult patients.	The King of Hearts Express® AF recorder is a patient-activated recorder designed for diagnostic evaluation of transient symptoms; such as dizziness, palpitations and syncope. The recorder provides single lead ECG morphology which may be used to visualize arrhythmias. It also provides automatic recording for detected Bradycardia, tachycardia or atrial fibrillation rhythms. Using looping memory, the King of Hearts Express® AF recorder captures ECG data, both before and after the patient experiences a cardiac symptom and the recording is activated. The patient wears the King of Hearts Express® AF recorder day and night while it continuously scans ECG activity. Upon activation, a cardiac event is recorded and stored in solid-state memory. Used in conjunction with a compatible telephonic ECG receiver or a receiving service, the King of Hearts Express® AF recorder provides a practical and convenient method for collecting diagnostic ECGs over an extended period of time for patients with symptoms suggesting a cardiac arrhythmia.
Anatomical Sites	Chest	Chest
Environment of Use	Outpatient (home) or Physician's Office	Outpatient (home) or Physician's Office
Analog/Digital	Digital	Digital
Input Impedance (Ohm)	5 Megohms (min)	3 Mohm
Electrode Configuration	1 or 2 lead /3 electrodes	1 Lead / 2 Electrodes
Frequency Response	0.05 - 100 Hz	0.05 - 40 Hz
CMRR (dB)	100 (min) dB 115 (typical) dB	60 dB
Input Dynamic Range (mVp-p)	1.75 V ± 1 µV	ECG input range @ 5Hz AC ±2 mV

		DC ±250 mV
Band Width (Hz)	0.05 - 100Hz	0.05 - 40 Hz
Pacemaker Pulse Marker	Yes	No
QRS Detection Sensitivity	Summary Results of AHA and MIT Testing **Database** / **QRS Se** / **QRS +P** **AHA** 97.84 99.55 **MIT-BIH** 98.96 99.27 **NST** 90.84 86.83 AHA - The American Heart Association Database for Evaluation of Ventricular Arrhythmia Detectors MIT-BIH - The Massachusetts Institute of Technology-Beth Israel Arrhythmia Database NST - The Noise Stress Database Se - Sensitivity: True Positive/True Positive + False Negative +P - Positive Predictivity: True Positive/True Positive + False Positive	Summary Results of AHA and MIT Testing **Database** / **QRS Se** / **QRS +P** **Combined Results AHA MIT and NST** 91.4 97.3 AHA - The American Heart Association Database for Evaluation of Ventricular Arrhythmia Detectors MIT-BIH - The Massachusetts Institute of Technology-Beth Israel Arrhythmia Database NST - The Noise Stress Database Se - Sensitivity: True Positive/True Positive + False Negative +P - Positive Predictivity: True Positive/True Positive + False Positive
System Communication/Monitoring	Continuous	Interrupted for communication
Maximum Storage Memory	64GB (30+ days)	10 minutes
Data Transmission	Cellular Transmission and Transtelephonic	Transtelephonic only
Includes Transtelephonic Capability	Yes	Yes
Heart Rate Indicators	Yes	Yes
Alarm System	Yes	No
Retrieval of Digital Holter Data	30 days	N/A
Maximum Days for Holter Analysis	30 days	N/A
Auto Detect/Auto Send	Yes	Yes/No
Manual Trigger	Yes	Yes
Power Input/Battery Type	3.7V Li-ion	2 - AAA
Battery Life	3 - 7 days	7 days
Low Battery Indication	Yes	Yes
Enclosure	Molded Plastic	Molded Plastic
ST Deviation	NEB Con	N/A
Number of Channels	1 or 2	1
Number of Electrodes	3	2
Number of Lead Sets	1	1
Storage Type (Digital or Tape)	Digital	Digital
Operating Temperature Range	0 to +45 °C	10 to 40 °C
Transport & Storage	0 to 65°C	-10 to 60 °C

Temperature		
Relative Humidity	10% - 95% Non-condensing	10% - 95% Non-condensing
Dimensions	5.3 x 2.8 x .8 inches	3.38 x 2.13 x .7 inches
Weight	7 oz	3.53 oz
ECG Algorithm	Applied Cardiac Systems, Inc. Automated ECG Analysis and Interpretation Software	Proprietary Algorithm for Detection of A-Fib
Real-Time ECG interpretation algorithm	Ventricular Fibrillation/Flutter, Atrial Fibrillation/Flutter, Pause (Asystole), Bradycardia, Tachycardia	Atrial Fibrillation/Flutter, Pause, Bradycardia, Tachycardia

ALARM & TRIGGER PREDICATE COMPARISON						
Project Name:	CORE Device					
Document Number:	CORE-ENG-SW-0048					
Document Owner:	ACS					
Date:	7/14/2011					
Rhythm	**Alarm**	**Setting**	**CORE**	**CG-6108**	**KOH EXP**	**Notes**
Ventricular Fibrillation/Flutter	Onset	Enabled	Y	N/A	N/A	
Ventricular Fibrillation/Flutter	Onset	Priority	1	N/A	N/A	
Ventricular Fibrillation/Flutter	Onset	Pre-Event (Seconds)	30	N/A	N/A	
Ventricular Fibrillation/Flutter	Onset	Post-Event (Seconds)	30	N/A	N/A	
Ventricular Fibrillation/Flutter	Offset	Enabled	Y	N/A	N/A	
Ventricular Fibrillation/Flutter	Offset	Priority	4	N/A	N/A	
Ventricular Fibrillation/Flutter	Offset	Pre-Event (Seconds)	0	N/A	N/A	
Ventricular Fibrillation/Flutter	Offset	Post-Event (Seconds)	0	N/A	N/A	
Atrial Fibrillation/Flutter	Onset	Enabled	Y	Y	Y	
Atrial Fibrillation/Flutter	Onset	Priority	1	1	N/A	
Atrial Fibrillation/Flutter	Onset	Pre-Event (Seconds)	30	60	60	
Atrial Fibrillation/Flutter	Onset	Post-Event (Seconds)	30	30	30	
Atrial Fibrillation/Flutter	Offset	Enabled	Y	Y	N/A	Offsets cannot be disabled for the ACT
Atrial Fibrillation/Flutter	Offset	Priority	4	1	N/A	
Atrial Fibrillation/Flutter	Offset	Pre-Event (Seconds)	0	60	N/A	
Atrial Fibrillation/Flutter	Offset	Post-Event (Seconds)	0	30	N/A	
Pause (Asystole)	Complete	Enabled	Y	Y	N/A	
Pause (Asystole)	Complete	Priority	1	1	N/A	
Pause (Asystole)	Complete	Duration (Seconds)	3	3	N/A	
Pause (Asystole)	Complete	Pre-Event (Seconds)	30	60	N/A	
Pause (Asystole)	Complete	Post-Event (Seconds)	30	30	N/A	
Bradycardia	Onset	Enabled	Y	Y	Y	AFX enables Tachy/Brady (single HR)
Bradycardia	Onset	Priority	1	1	N/A	
Bradycardia	Onset	Threshold (BPM)	40	40	30	
Bradycardia	Onset	Duration (Seconds)	5	25	N/A	Duration is not a settable value
Bradycardia	Onset	Pre-Event (Seconds)	30	60	60	
Bradycardia	Onset	Post-Event (Seconds)	30	30	30	
Bradycardia	Offset	Enabled	Y	Y	N/A	Offsets cannot be disabled for the ACT
Bradycardia	Offset	Priority	4	1	N/A	
Bradycardia	Offset	Threshold (BPM)	40	40	N/A	
Bradycardia	Offset	Duration (Seconds)	5	20	N/A	
Bradycardia	Offset	Pre-Event (Seconds)	0	60	N/A	
Bradycardia	Offset	Post-Event (Seconds)	0	30	N/A	

Tachycardia	Onset	Enabled	Y	Y	Y	AFX enables Tachy/Brady (single HR)
Tachycardia	Onset	Priority	1	1	N/A	
Tachycardia	Onset	Threshold (BPM)	160	150	150	
Tachycardia	Onset	Duration (Seconds)	3	10	N/A	Duration is not a settable value
Tachycardia	Onset	Pre-Event (Seconds)	30	60	60	
Tachycardia	Onset	Post-Event (Seconds)	30	30	30	
Tachycardia	Offset	Enabled	Y	Y	N/A	Offsets cannot be disabled for the ACT
Tachycardia	Offset	Priority	4	1	N/A	
Tachycardia	Offset	Threshold (BPM)	160	150	N/A	
Tachycardia	Offset	Duration (Seconds)	3	10	N/A	
Tachycardia	Offset	Pre-Event (Seconds)	0	60	N/A	
Tachycardia	Offset	Post-Event (Seconds)	0	30	N/A	
User	Complete	Enabled	Y	Y	Y	
User	Complete	Priority	1	1	N/A	
User	Complete	Pre-Event	30	60	60	
User	Complete	Post-Event	30	30	30	

Table 5.1.2 Alarm and Trigger Predicate Comparison

LEGEND
Cannot be set in this device
Only a global setting, not individual
Not Applicable

5-1-3: CORE™ vs. Monebo Automated ECG Analysis and Interpretation Software Library, Version 3.0 (K062282)

Table compares the ECG QRS Trigger and Arrhythmia Detection Algorithm functionality for MCT mode	Applied Cardiac Systems, Inc. The CORE™ (Subject Device)	Monebo Technologies, Inc. Monebo Automated ECG Analysis And Interpretation Software Library, Version 3.0 (Predicate Device)
Manufacturer	Applied Cardiac Systems, Inc.	Monebo Technologies, Inc.
510(k) Number	Class II, DPS, 870.2340, DSI, 870.1025, DSH, 870.2800	K062282 Class II, DPS, 870.2340
Intended Use	MCT mode	Analysis mode
Anatomical Sites	Chest	Chest
Environment of Use	Physician Office / Hospital	Physician Office / Hospital
ECG Algorithm	Applied Cardiac Systems, Inc. Automated ECG Analysis and Interpretation Software	Monebo Technologies, Inc. Monebo Automated ECG Analysis And Interpretation Software Library

Section 5-1-3-1: Algorithm Results

Accuracy of Arrhythmia Statements & Predicate Comparisons												
Arrhythmias	**Event (Ese) Sensitivity**			**Event (E+P) Positive Predictive Accuracy**			**Duration (Dse) Sensitivity**			**Duration (D+P) Positive Predictive Accuracy**		
	ACS[1]	Monebo[2]	KOH[3]	ACS[1]	Monebo[2]	KOH[3]	ACS[1]	Monebo[2]	KOH[3]	ACS[1]	Monebo[2]	KOH[3]
Ventricular Fibrillation/ Flutter[7,8,9]	99	100	NA	100	NA[5]	NA	92	NA	NA	97	NA	NA
Atrial Fibrillation/ Flutter[7,10]	96	100	88	90	77[11] (70)	81	97	NA	70	93	NA	55
Pause (Asystole)[7]	99	Insufficient Data[4]	NA	100	Insufficient Data[4]	NA	98	Insufficient Data[4]	NA	96	Insufficient Data[4]	NA
Bradycardia[7,8,10]	97	Insufficient Data[4]	NA	79	Insufficient Data[4]	NA	93	NA	NA	76	NA	NA
Tachycardia[7,8,10]	92	Insufficient Data[4]	NA	100	Insufficient Data[4]	NA	87	NA	NA	95	NA	NA

Table 5.1.3.1 ACS CORE Accuracy of Arrhythmia Detection and Comparison to Predicate Devices

1. Applied Cardiac Systems, Inc CORE MCT
2. Monebo Automated ECG Analysis and Interpretation Software Library, K062282 predicate device for comparison purposes
3. Card Guard Scientific Survival Ltd. King of Hearts (KOH) Express+AF Monitor (with Alarms and Triggers), K020825
4. Monebo reports "Insufficient data" (ACS was able to collect sufficient data from the AHA, MIT & NST databases. Reference Section 3.4)
5. Monebo reports "Positive Predictive and Negative Accuracy cannot be calculated because all records contain VF"
6. KOH reports Episode/Duration Sensitivity & Episode/Duration positive predictivity
7. MIT_BIH - Massachusetts Institute of Technology Beth Israel Hospital Arrhythmia Database
8. AHA - American Heart Association Database for the Evaluation of Ventricular Arrhythmia Detectors
9. CU - Creighton University Sustained Ventricular Arrhythmia Database
10. NST - Noise Stress Test Database
11. Monebo predicate reports 100% for Se, Sp, and -P but 77% for +P. Since the +P is reported as 77%, this implies a Sp of 70% not 100%. It is also unclear if the Monebo predicate is reporting on AF episodes or AF durations. AF episodes is assumed.

Feature	Applied Cardiac Systems, Inc CORE MCT	Monebo Automated ECG Analysis and Interpretation Software Library K062282	Card Guard Scientific Survival Ltd. KOH Express+AF Monitor K020825
Heart rate determination for non-paced adult	YES	YES	YES
QRS Detection	YES	YES	YES
VF arrhythmia interpretation for adult patients	YES	YES	NO
AF arrhythmia interpretation for adult patients	YES	YES	YES
Non-paced ventricular arrhythmia calls for adult patients	NO	YES	NO
Intervals measurement	YES	YES	NO
Ventricular ectopic beat detection	NO	YES	NO
Patient Populations	ADULT	ADULT	ADULTS
Alarms & Triggers	YES	NO	YES

Table 5.1.3.2 Feature Comparison of ACS CORE MCT with Predicate Device

Summary results of AHA, MIT, and NST testing				
Database	**QRS Se**		**QRS +P**	
	ACS CORE	**Monebo Automated ECG Analysis and Interpretation Software Library**	**ACS CORE**	**Monebo Automated ECG Analysis and Interpretation Software Library**
AHA	97.84	99.56	99.55	99.9
MIT-BIH	98.96	99.45	99.27	99.45
NST	90.84	91.56	86.83	85.66

Table 5.1.3.3 ACS CORE QRS / VEB Results

Accuracy of Arrhythmia Detection			
Event Sensitivity	**Event Predictivity**	**Duration Sensitivity**	**Duration Predictivity**
97.59	94.85	97.35	94.30
Arrhythmias: Ventricular Fibrillation/Flutter, Atrial Fibrillation/Flutter, Pause (Asystole), Bradycardia, Tachycardia			

Table 5.1.3.4 ACS CORE Accuracy Arrhythmia Detection

5-1-4: CORE™ vs. The Holter Reporter™ (K860249)

Table compares the CORE™ Receiving Module Software functionality for MCT mode	Applied Cardiac Systems, Inc. The CORE™ (Subject Device)	Applied Cardiac Systems, Inc. The Holter Reporter™ (Predicate Device)
Manufacturer	Applied Cardiac Systems, Inc.	Applied Cardiac Systems
510(k) Number	Class II, DPS, 870.2340, DSI, 870.1025, DSH, 870.2800	K860249 Class II, DPS, 870.2340
Intended Use	Resting 12-lead EKG	3,12-lead ECG
Anatomical Sites	Chest, Arms, Legs	Chest
Environment of Use	Physician Office / Hospital	Physician Office / Hospital
Real-time 12-lead ECK	Yes	Yes
Preview	Yes	Yes
Monitor	Yes	Yes
802.15.4 Transceiver	Yes	No
Storage	Up to 64 GB	300 GB
Capture Mode	Yes	Yes
Transmit Wireless	Yes	Yes
3+1, outputs	Yes	Yes
3+3 output	Yes	Yes
6-channel output	Yes	Yes
12-channel output	Yes	Yes
Connectivity Options	USB, 802.15.4, Cellular Modem, Bluetooth	LAN,USB
Information Exchange Interfaces	EMR-HL-7,XML,PDF	EMR-HL-7,XML,PDF
ECG Algorithm	Applied Cardiac Systems, Inc. Automated ECG Analysis and Interpretation Software (K860249)	Applied Cardiac Systems, Inc. Automated ECG Analysis and Interpretation Software
Resting ECG interpretation algorithm	1. SINUS RHYTHM 2. SINUS BRADYCARDIA 3. SINUS TACHYCARDIA 4. PREMATURE JUNCTIONAL CONTRACTION 5. JUNCTIONAL TACHYCARDIA 6. FIRST DEGREE HEART BLOCK + SINUS RHYTHM 7. FIRST DEGREE HEART BLOCK + SINUS TACHYCARDIA 8. FIRST DEGREE HEART BLOCK + SINUS BRADYCARDIA 9. SECOND DEGREE HEART BLOCK TYPE I	1. SINUS RHYTHM 2. SINUS BRADYCARDIA 3. SINUS TACHYCARDIA 4. PREMATURE JUNCTIONAL CONTRACTION 5. JUNCTIONAL TACHYCARDIA 6. FIRST DEGREE HEART BLOCK + SINUS RHYTHM 7. FIRST DEGREE HEART BLOCK + SINUS TACHYCARDIA 8. FIRST DEGREE HEART BLOCK + SINUS BRADYCARDIA 9. SECOND DEGREE HEART BLOCK TYPE I

	10. SECOND DEGREE HEART BLOCK TYPE II 11. THIRD DEGREE (COMPLETE) HEART BLOCK 12. PREMATURE ATRIAL CONTRACTION 13. SUPRAVENTRICULAR TACHYCARDIA 14. ATRIAL FIBRILLATION/FLUTTER SVR 15. ATRIAL FIBRILLATION/FLUTTER CVR 16. ATRIAL FIBRILLATION/FLUTTER RVR 17. PAUSE 18. PREMATURE VENTRICULAR CONTRACTION 19. VENTRICULAR COUPLET 20. VENTRICULAR TRIPLET 21. VENTRICULAR BIGEMINY 22. VENTRICULAR TRIGEMINY 23. IDIOVENTRICULAR RHYTHM 24. VENTRICULAR TACHYCARDIA 25. SLOW VENTRICULAR TACHYCARDIA 26. VENTRICULAR FLUTTER 27. ARTIFACT	10. SECOND DEGREE HEART BLOCK TYPE II 11. THIRD DEGREE (COMPLETE) HEART BLOCK 12. PREMATURE ATRIAL CONTRACTION 13. SUPRAVENTRICULAR TACHYCARDIA 14. ATRIAL FIBRILLATION/FLUTTER SVR 15. ATRIAL FIBRILLATION/FLUTTER CVR 16. ATRIAL FIBRILLATION/FLUTTER RVR 17. PAUSE 18. PREMATURE VENTRICULAR CONTRACTION 19. VENTRICULAR COUPLET 20. VENTRICULAR TRIPLET 21. VENTRICULAR BIGEMINY 22. VENTRICULAR TRIGEMINY 23. IDIOVENTRICULAR RHYTHM 24. VENTRICULAR TACHYCARDIA 25. SLOW VENTRICULAR TACHYCARDIA 26. VENTRICULAR FLUTTER 27. ARTIFACT
Full Keyboard	Yes	Yes
Full-Size, 8½ x 11	Yes	Yes

5-1-5: CORE™ vs. Model 950-12L (K102723)

Table compares the Holter functionality mode	Applied Cardiac Systems, Inc. CORE™ (Subject Device)	Memtec Corporation Model 950-12L (Predicate Device)
Manufacturer	Applied Cardiac Systems, Inc.	Memtec Corporation
510(k) Number	Class II, DSH, 870.2800, DSI, 870.1025, DPS, 870.2340	K102723 Class II, MWJ, 870.2800
Intended Use	Holter Monitoring	Holter Monitoring
Anatomical Sites	Chest, Arms, Legs	Chest
Environment of Use	Physician Office / Hospital	Physician Office / Hospital
Sample Rate	256,512,1024,2048 (3 & 12-chan) Oversample rate: up to 32,000 samples per second	Selectable 128, 256, 512, or 1024 samples per second
A/D Resolution (bits)	16-20 at 3.25µV/Bit	Selectable 8, 10 or 12 bits per channel with 6K SPS over-sampling per channel
Bandwidth	0.05-100Hz (0.05-125KHz Pacer)	0.05 to 60 Hz. (-3 db)
Battery	3.7V Li-Ion with auto shutdown when battery is exhausted (protecting against battery leakage). Not user changeable.	One AA alkaline, lithium, or rechargeable NiMH battery with reverse polarity protection and auto shutdown when battery is exhausted (protecting against battery leakage)
Pacemaker Detection	Yes	Yes
Lead Sets	12 Lead (optional 3 channel 5 lead available)	12 Lead patient Cable (optional 3 channel 5 or 7 lead available)
USB 2.0 Download	Yes	Yes
Cellular Download	Yes	No
Data Integrity	ECC & MD5 every Min	Patient ID, date, and time stamped records with CRC-16 in 2 min. intervals (patent pending)
LCD Screen	3.2" TFT 256K Colors	Large monochrome 119 x 73 LCD display
Keyboard	5-Button	5-button
Touchscreen	Yes	No
SDHC Flash Storage	Up to 64 GB	SD or SDHC storage card (up to 4GB, removable)
USB Built into Cable set	No – Cable set needs to be removed – uses custom USB cable	No – Cable set needs to be removed – uses standard USB mini Cable
USB Charging	No	No
Power Wall Charger	Yes	No
Maximum Recording Duration	5 days @2048 SPS 12-Chan	Up to 48 hours in 12 lead mode / In 3 Channel Mode; up to 120

		hours

5-1-6: CORE™ vs. EK10 (K870880)

Table compares the Resting 12-lead EKG functionality mode	Applied Cardiac Systems, Inc. The CORE™ (Subject Device)	Burdick Corp. EK10 Electrocardiograph (Predicate Device)
Manufacturer	Applied Cardiac Systems, Inc.	Burdick Corporation
510(k) Number	Class II, DPS, 870.2340, DSI, 870.1025, DSH, 870.2800	K870880 Class II, DPS, 870.2340
Intended Use	Resting 12-lead EKG	Resting 12-lead EKG
Anatomical Sites	Chest, Arms, Legs	Chest, Arms, Legs
Environment of Use	Physician Office / Hospital	Physician Office / Hospital
Real-time 12-lead EKG	Yes	Yes
Preview	Yes	No
Monitor	Yes	No
802.15.4 Transceiver	Yes	No
Storage	Up to 64 GB	None
Capture Mode	Yes	N/A
Transmit Wireless	Yes	N/A
3+1, outputs	Yes	One channel at a time
3+3 output	Yes	One channel at a time
6-channel output	Yes	One channel at a time
12-channel output	Yes	One channel at a time
Information Exchange Interfaces	EMR-HL-7,XML,PDF	N/A
Input Impedance (Ohm)	5 Megohms (min)	Greater than 50 Mohm
Power/Input/Battery Type	3.7V Li-ion AC power N/A	12.5Vdc nickel-cadmium 120Vac
Operating Temperature Range	0 to +45 °C	10 deg. C to 40 deg. C
Transport & Storage Temperature	0 to 65 °C	-34 deg. C to 70 deg. C
Relative Humidity	10% to 95% Non-condensing	15% to 90% Non-condensing
Dimensions	5.3 x 2.8 x.8 inches	11 x 13 x 3-3/16 inches
Weight	7 oz.	9 lb. (including optional battery)
ECG Algorithm	N/A	N/A
Resting ECG interpretation algorithm	No	No
Full Keyboard	Multiple choice menu buttons	Multiple choice menu buttons

As is evident from the above discussion, none of the above differences raises a question of safety and effectiveness, and the CORE™ device remains substantially equivalent to its predicate devices in indications and intended use, safety, and effectiveness.

Referenced Standards:

Prior to marketing the CORE™ device, verification testing activities will be conducted to meet specified acceptance criteria and establish compliance, performance and reliability characteristics of the CORE™ device. This is to include all applicable acceptance criteria and tests in the applicable standards; a statement of conformity to the standards is not made until testing has been completed.

Consensus Standards:

Included are the forms FDA FORM 3654 (as replicated by Applied Cardiac Systems), completed for each of the following consensus standards:

- IEC 60601-1-2 Ed 2.1:2004, (Ed 2:2001 with Amendment 1:2004); Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests;
- ANSI/AAMI EC13:2002(R) 2007, Cardiac monitors, heart rate meters and alarms;
- ANSI/AAMI EC53:1995/(R) 2008, ECG cables and leadwires;
- AAMI/ANSI EC57:1998/(R) 2003, Testing and Reporting Performance Results of Cardiac Rhythm and ST-Segment Measurement Algorithms;

Other standards:

Also included in this submission are FDA FORM 3654 (as replicated by Applied Cardiac Systems) completed for the following other standard.

- IEC 60601-1 Ed 2:1988, Amendment 1:1991, Amendment 2:1995; Medical Electrical Equipment Part 1: General requirements for safety (IEC 60601-1 Ed 2:1988, is the general standard to IEC 60601-1-2 Ed 2.1:2004 and as such is part of the consensus standard IEC 60601-1-2).
- IEC 60601-1-4:1999, General requirements for basic safety and essential performance – Collateral standard Programmable electrical medical systems.
- ANSI/AAMI EC11:1991/(R) 2007, Diagnostic electrocardiographic devices.
- AAMI/ANSI EC38:2007, Medical electrical equipment – Part 2–47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems.
- 21 CFR Part 898, Performance Standard for Electrode Lead Wires and Patient Cables;

Additional testing:

The following documents at the end of this section address the request for additional testing documentation:

1. ACS document number CORE-ENG-HW-0006 titled MCT Hardware Requirements Specification (MCT Recorder)
2. ACS document number CORE-ENG-HW-0008 titled Main Board Requirements Specification (MCT Recorder)
3. ACS document number CORE-ENG-HW-0010 titled ACS ECG Data Acquisition Module Specification
4. ACS document number CORE-ENG-HW-0007 titled MCT Hardware Test Requirements Specification (MCT Recorder)
5. ACS document number MS9-ENG-SW-0011 titled M9 CORE™ Processing Module Validation Test Plan

Substantial Equivalence Conclusion:

The CORE™ mobile cardiac telemetry (MCT) device by Applied Cardiac Systems, Inc. essentially has the same intended use and similar operating principles and technical characteristics as the predicate devices. It will be subjected to the same set of performance and safety tests as the predicate devices, as described in the Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm. Based upon the comparisons made, the CORE™ is safe, effective and poses no adverse health or safety risks and is therefore substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Applied Cardiac Systems, Inc
c/o Mr. Ben Ghadimi
22912 El Pacifico Drive
Laguna Hills, CA 92653

AUG 24 2011

Re: K103706
Trade Name: The CORE (Cardiac Outpatient Realtime ECG)
Regulation Number: 21 CFR 870.1025
Regulation Name: Detector and Alarm, Arrhythmia
Regulatory Class: Class II (two)
Product Code: DSI
Dated: August 9, 2011
Received: August 17, 2011

Dear Mr. Ghadimi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for use

510(k) Number (if known): K103706

Device Name: The CORE™ (Cardiac Outpatient Realtime ECG)

Indications for Use:

1. MCT Mode: Use on adult patients who experience transient or non-transient symptoms that may suggest cardiac arrhythmias. The arrhythmia detector and alarm device monitors an electrocardiogram and is designed to produce a visible or audible signal or alarm when Ventricular Fibrillation/Flutter, Atrial Fibrillation/Flutter, Pause (Asystole), Bradycardia, or Tachycardia occurs.

2. Holter Mode: Use on adult patients experiencing palpitations, syncope, pre-Syncope, dizziness, arrhythmia, bradycardia, tachycardia, angina, ischemia and paced ECG.

3. Multi-Lead (Resting EKG) Mode: Use on adult patients for acquiring, storing and viewing/printing of up to twelve (12) leads of patient ECG waveforms through surface electrodes adhered to the patient's body.

Contra-indications for use:

1. Patients with potentially life-threatening arrhythmias who require inpatient monitoring; and patients who the attending physician thinks should be hospitalized.

The device continuously monitors patient's ECG, automatically generates an alarm triggered by an arrhythmia detection algorithm or generates an alarm manually triggered by the patient, and transmits the recorded data transtelephonically to a monitoring center.

The software does not perform diagnosis. The ECG data is provided to the medical practitioner for evaluation and diagnosis.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103706